

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Drug Safety and Risk Management Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 9, 2006 from 8 a.m. to 5 p.m. and February 10, 2006, from 8 a.m. to 3 p.m.

Location: Holiday Inn Gaithersburg, Two Montgomery Village Avenue, Gaithersburg, MD.

Contact Person: Victoria Ferretti-Aceto, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, (301) 827-7001, fax: (301) 827-6776, e-mail: ferrettiv@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512535. Please call the Information Line for up-to-date information on this meeting. When available, background materials for this meeting will be posted on FDA's Web site one business day before the meeting at: <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2006 and scroll down to Drug Safety and Risk Management Advisory Committee).

Agenda: Cases of sudden death and serious adverse events including hypertension, myocardial infarction, and stroke have been reported to the

Agency in association with therapeutic doses of drugs used to treat Attention Deficit Hyperactivity Disorder (or ADHD) in both pediatric and adult populations. The few controlled clinical studies of longer term drug treatment of ADHD provided little information on cardiovascular risks. On February 9, 2006, the committee will be asked to discuss approaches that could be used to study whether these products increase the risk of adverse cardiovascular outcomes. On February 10, 2006, the committee will be briefed on developments in the Office of Drug Safety and will receive updates on the Drug Safety Oversight Board and Agency actions for the COX-2 selective Nonsteroidal Anti-inflammatory Drugs (NSAIDs) and the risk management program for the isotretinoin products.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 2, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on February 9, 2006, and between approximately 8:15 a.m. and 9:15 a.m. on February 10, 2006. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 2, 2006, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation. Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Victoria Ferretti-Aceto at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated _____

Victoria Ferretti-Aceto
Executive Secretary

Dated _____

Dornette Spell-Lesane
Supervisory Team Leader